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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,610	02/12/2001	Jonathan Stanley Harold Denyer	011150US	3883
	7590 04/02/201 LLECTUAL PROPER	EXAMINER		
P.O. BOX 3001		MENDOZA, MICHAEL G		
BRIARCLIFF MANOR, NY 10510			ART UNIT	PAPER NUMBER
			3734	
			MAIL DATE	DELIVERY MODE
			04/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary		Ap	plication No.	Applicant(s)				
		09)/781,610	DENYER ET AL.				
		Ex	aminer	Art Unit				
		MI	CHAEL G. MENDOZA	3734				
 Period for	The MAILING DATE of this communi Reply	cation appears	on the cover sheet with the c	orrespondence address				
A SHOI WHICH - Extensic after SI - If NO pe - Failure Any rep	RTENED STATUTORY PERIOD FOR EVER IS LONGER, FROM THE MOTE OF THE O	AILING DATE of 37 CFR 1.136(a). unication. ututory period will ap will, by statute, caus	OF THIS COMMUNICATION In no event, however, may a reply be timely and will expire SIX (6) MONTHS from the application to become ABANDONEI	l. ely filed the mailing date of this communication (35 U.S.C. § 133).				
Status								
1)⊠ R	esponsive to communication(s) file	d on <i>03 Jun</i> e :	2009					
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,—	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
	n of Claims	20 011001 2 21 po		0 0.0.2.0.				
•								
· —	Elaim(s) <u>1,3,7,8,12,21,39-41,44,51-(</u>			n.				
	4a) Of the above claim(s) is/are withdrawn from consideration.							
·	5) Claim(s) is/are allowed.							
·	flaim(s) <u>1,3,7,8,12,21,39-41,44,51-6</u>	<u>53 and 1316</u> IS	/are rejected.					
•	laim(s) is/are objected to.	tion and/on ala	ation vacuinament					
8)[0	laim(s) are subject to restric	uon and/or eie	ction requirement.					
Application	n Papers							
9)□ Tł	ne specification is objected to by the	e Examiner.						
10)∐ Tł	ne drawing(s) filed on is/are:	a)∏ accepte	d or b) \square objected to by the E	xaminer.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
R	eplacement drawing sheet(s) including	the correction is	s required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).			
11)□ Tł	ne oath or declaration is objected to	by the Exami	ner. Note the attached Office	Action or form PTO-152.				
Priority un	der 35 U.S.C. § 119							
a) <u></u>	cknowledgment is made of a claim a All b) Some * c) None of: Certified copies of the priority			-(d) or (f).				
2	 Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No 							
	3. Copies of the certified copies of the priority documents have been received in this National Stage							
	application from the International Bureau (PCT Rule 17.2(a)).							
* Se	e the attached detailed Office action	•		d.				
Attachment(s)							
	of References Cited (PTO-892)		4) Interview Summary					
	of Draftsperson's Patent Drawing Review (P tion Disclosure Statement(s) (PTO/SB/08)	TO-948)	Paper No(s)/Mail Da 5) Notice of Informal P					
Paper N	• •							

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DETAILED ACTION

Response to Arguments

- 1. Applicant's arguments filed 6/3/2009 have been fully considered but they are not persuasive.
- 2. The applicant argues that Gordon fails to teach a drug <u>adapted</u> for delivery in air inhaled by a patient to their lungs. The limitation is a function limitation and is treated as such since the drug delivery device is not positively claimed. Furthermore, it is well know in the art that capsules can carry powders and that powders can be inhaled (evidenced by Anderson).
- 3. The applicant argues that Gordon does not teach a drug delivery device. The applicant has not positively claimed a drug delivery device in claim 1.
- 4. The applicant argues that Gordon does not teach a radio frequency device. The examiner disagrees. Gordon teaches a transmitter 70 capable of transmitting information. The applicant has not positively claimed the drug delivery device in claim 1.
- 5. For transmitting the drug treatment information to the drug delivery device is a function limitation and is treated as such since the drug delivery device is not positively claimed.
- 6. The applicant argues that Gordon does not teach a drug delivery device. The applicant has not positively claimed a drug delivery device in claim 1. The only positively claimed limitations in claim 1 are: at least one container; a removable

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electronic data carrier; a memory; and a radio frequency device. Gordon meets all of the claimed limitations.

- 7. As to claim 19, the applicant argues that Gordon does not teach a drug delivery device. The examiner disagrees. The applicant has not given any structural limitations in the claims as to what the drug delivery device comprises. The device of Gordon holds at least one container. The device is then opened and a container is delivered to a patient. Gordon also teaches an electronic data carrier; a memory; and an output.
- 8. As to claim 20, the applicant argues that Gordon does not teach a drug delivery device. The examiner disagrees. The applicant has not given any structural limitations in the claims as to what the drug delivery device comprises besides a chamber for receiving a drug. The device of Gordon teaches chambers into with capsules with drugs are placed. Gordon also teaches an electronic data carrier; and a radio frequency input (74).
- 9. As to claims 39 and 40, the containers of Gordon are capsules, capsules can contain powders or liquids, powders and liquids are known to be inhaled as evidenced by Anderson. The applicant has not specified what the drug comprises. Furthermore, the applicant has not positively claimed a drug delivery device. The applicant has only claimed that the drugs are *for* a drug delivery device.
- 10. The applicant argues that Gordon does not read on claim 47. Claim 47 has been cancelled by the applicant.
- 11. As to claims 13 and 19, the applicant argues that Anderson et al. a delivery controller for controlling the amount of the drug delivered to the patient based on

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receive treatment information. The examiner disagrees. The controller of Anderson uses instructions stored on removable memory (see claim 5). The instructions include treatment information on how to treat the user and includes information for use of a nebulizer.

- 12. As to claims 16-18, Anderson teaches an authorization portion (alarms), and wherein the drug delivery device is selected from one of a pneumatic nebulizer, a piezo-electric nebulizer, or an ultrasonic nebulizer (Anderson is an air driven/pneumatic nebulizer). The examiner is not relying on Gordon for the teaching of drug capsules/tablets or for a blister package. The Gordon reference is used as a teaching reference for only radio transmission of information.
- 13. Claims 2, 4-6, 9-11, 14, 15, 22-38, 42, 43, and 45-50 are cancelled.
- 14. Claims 57-63 are newly added.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 16. Claims 1, 3, 4, 7, 8, 12, 19-21, 54, 58-59, 60, 62, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon 4617557.
- 17. Gordon teaches a drug package comprising: a least one container containing a drug; an electronic data carrier including a memory, the electronic data carrier further includes a radio frequency device; wherein the electronic data carrier is arranged to

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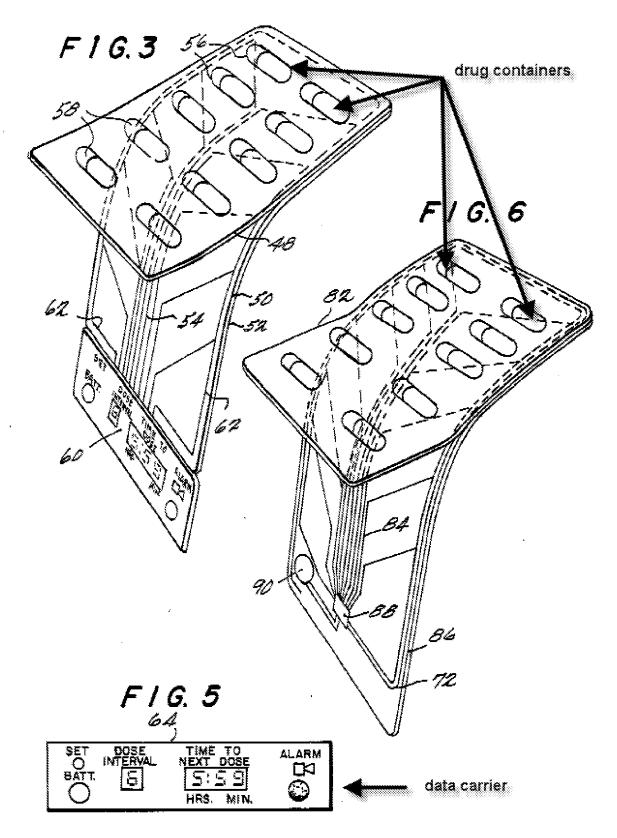
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supply the drug treatment information a number of times corresponding to the number of treatments available from the drug package, or the number of containers included in the drug package (col. 2, lines 22-30); wherein the at least one container is a plurality of containers and wherein the electronic data carrier is a single electronic data carrier; wherein the memory stores information; wherein the drug treatment information includes at least one of the following items: an identity of the drug which is to be delivered; a security code; a desired amount; a desired frequency of treatment; or an expiration date (col. 2, lines 22-30); a radio frequency transmitter (70) and a radio frequency receiver (74).

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- 18. As to claim 57, the at least one container can be read as the blister pack, the first container can be considered one capsule, and the blister pack can be considered a single compartment. All the capsules are contained within the single compartment of the blister pack.
- 19. As to claim 59, it has been held that to be entitled to weight in method claims, the recied structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

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Claim Rejections - 35 USC § 103

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20. Claims 39-41, 44, 48, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon in view of Chartrand 5562550.

- 21. As to claim 39 and 40, Gordon teaches a plurality of drug containers, each container containing a drug; and an electronic data carrier separate from the drug containers, the carrier including drug treatment information. It should be noted that Gordon fails to teach wherein the data carrier is arranged to be powered inductively from a radio frequency signal. Gordan teaches that the data carrier is powered via a battery.
- 22. Chartrand teaches a device with a data carrier arranged to be powered inductively from a radio frequency signal as opposed to the battery powered data carrier taught by Gordon. Therefore, it would have been obvious to use a data carrier arranged to be powered inductively from a radio frequency signal an alternative to battery powered data carrier, because they are expedients of eachother. Furthermore, inductively powered data carriers are well known in the art of electronics.
- 23. Gordon/Chartrand teaches wherein the drug treatment information includes at least one of the following items: an identity of the drug which is to be delivered; a security code; a desired dose amount; a desired frequency of treatments; or an expiration date of the drug (col. 2, lines 22-30).
- 24. Claims 1, 13, 19, and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. 5237987 in view of Gordon.

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25. As to claims 13 and 19, Anderson et al. teaches a drug delivery device; a delivery portion (52); an electronic input (228) arranged remotely from the delivery portion; and electronic data carrier removable from the drug delivery device (see claim 5); a delivery controller (28); a memory located within the electronic data carrier; and an output. It should be noted that Anderson et al. fails to teach transmitting treatment information via a radio frequency signal.

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- 26. Gordon teaches a device with an output for transmitting treatment information via a radio frequency signal as opposed to the circuitry taught by Anderson et al. for transmitting information. Therefore, it would have been obvious to use a radio frequency signal as an alternative to circuitry for transmitting information because they are expedients of eachother. Furthermore, wireless connectively is well known in the art of electronics.
- 27. As to claims 16-18, 51, and 52, Anderson/Gordon teaches the device according to claim 13, wherein the drug delivery device includes an authorization portion (col. 12, lines 11-18); wherein the drug delivery device is selected from one of a pneumatic nebulizer, a piezo-electric nebulizer, or an ultrasonic nebulizer (Anderson is an air driven/pneumatic nebulizer).

Conclusion

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/M. G. M./ Examiner, Art Unit 3734

/Todd E Manahan/ Supervisory Patent Examiner, Art Unit 3734